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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,621	11/02/2001	Artur Mitterer	20695D-000110US	6242

20350 7590 12/15/2003

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/003,621

**Applicant(s)**

MITTERER ET AL.

**Examiner**

Hope A. Robinson

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The preliminary amendment filed November 2, 2001 has been received and entered.  
Claims 1-16 have been canceled and new claims 17-22 have been added.

### ***Specification***

2. The disclosure is objected to because of the following informalities:

The specification is objected to because trademarks are disclosed and they are not capitalized. The use of the trademark such as Toyopearl®, Fast Flow®, Fractogel® etc., has been noted in this application (see pages 7, 24 and 27 for example). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Correction is required.

### ***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in on February 27, 1997. It is noted, however, that applicant has not filed a certified copy of the application (Austria A 338/97) as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-22 are rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 17 and the dependent claims hereto are indefinite for the recitation of "vWF" as this acronym could mean "Vincent William Flack", therefore, at the independent claim need to recite the spelled out meaning "von Willebrand Factor".

Claim 18 is indefinite for the recitation of "particularly free" as it is unclear what the metes and bounds of the claim are and the specification does not define this phrase, it is suggested that the claim is amended to recite "free".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

6. Claims 17-22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Arrighi et al. (EP 600480, December 4, 1993) in view of Fischer et al. (EP 705846, October 4, 1996).

Arrighi et al. disclose a factor VIII-von Willebrand Factor complex extracted from total plasma comprising purification via a cationic exchanger (claim 17). The process disclosed by Arrighi et al. enables obtaining a FVIII:C-vWF with high purity (claim 18). Arrighi et al. also teach that the FVIII:C-vWF complex is virus free (claim 20) due to a process of viral inactivation and the removal of other contaminants (claim 18); and the process obtains an FVIII:C-FvW with high purity (specific activity and yield (claim 19)). Arrighi et al. teaches a specific activity of 30-50 IU/mg it is assumed to be equivalent to the claimed amounts recited in claim 19 (see columns 2 and 5 of the reference). Note, that the specification reports on page 19, "a 20-fold purification of FVIII (specific activity :12 IU FVIII:C/mg protein" and the reference teaches "8-15 IU of FVIII/mg of protein" (column 5), thus it is assumed the reference achieved a purity that

Art Unit: 1653

is equal or higher than the claimed invention. Additionally, Arrighi et al. teach that the process used to extract the Factor VII:C/vWF-complex addresses problems found with other methods such as instability and the requirement for addition of several stabilizers (claim 21, column 1 of the reference). Arrighi et al. does not *per se* teach a pharmaceutical preparation, however, the reference teach that there is a need for having available larger amounts of Factor VIII concentrates for application of a suitable prophylactic treatment and that all hemophiliac A in the world could be treated ( claim 22, column 1). In addition, Fischer et al. disclose a chromatographic method for separating the high and low molecular weight forms of vWF and a treatment regimen with pharmaceutical preparation (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because Arrighi et al. teach a process for the extraction of factor VIII-von Willebrand Factor complex comprising a cationic exchanger, yielding a product with high specificity and purity. In addition, Arrighi et al. provides suggestions for a pharmaceutical preparation and state that their process used resolves issues of instability of the product. In-so-far-as Arrighi et al. does not explicitly teach a pharmaceutical, Fischer et al. discloses a treatment regimen and the use of said product in a pharmaceutical. One of ordinary skill in the art would be motivated to combine the teachings of the references because Arrighi et al. discloses the importance and necessity of having larger amounts of FVIII concentrates for treatment. Thus, the claimed invention was obvious to make and use at the time it was made and was *prima facie* obvious.

***Conclusion***

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:00 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner

  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600